REMARKS

Favorable reconsideration of this application is respectfully requested.

Claims 6-25 are pending in this application. Claims 18-25 are added by the present response. Claims 6-13 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. patent no. 5,385,564 to Slater et al. (herein "Slater"), U.S. patent 5,484,431 to Scharf et al. (herein "Scharf"), or U.S. patent 4,282,863 to Beigler et al. (herein "Beigler"). Claims 6-17 were also rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. patent 3,726,276 to Schumann et al. (herein "Schumann") in view of Slater, Scharf, or Beigler.

Before addressing the above-noted rejections in detail, a brief review of the present invention is believed to be helpful.

The applicants of the present invention recognized that a problem exists in the current art in that until the present invention it was not possible to have a bag in which a ready to use solution could be reconstituted from a sterile product such that the sterile product could be reconstituted directly into the bag still under sterile conditions to form solutions that could then be taken out from the bag as a whole all at one time or as partial (e.g., single doses) portions of the total volume of the reconstituted solution. (Substitute specification page 4, lines 5-12).

As discussed in the present specification, a bag in which a sterile product is formed and which must be completely filled with a solvent to form a solution has been realized. (Substitute specification, page 3, lines 12-14). However, the drawback with that type of device is that since the bag must be completely filled with the solvent a complete solution of the powder cannot be attained by simply shaking the bag, and therefore the bag must require additional devices for creating turbulence within the bag. (Substitute specification, page 3, lines 14-19). Further, since the bag is always completely filled, the bag must always start out with the same amount of soluble sterile product.

Claims 6-11 set forth, and with reference to Figures 1-5, an improved bag 1 such that the volume of the bag 1 is larger than the volume of the reconstituted ready to use solution after the reconstitution. (Substitute specification, page 6, lines 11-14, page 7, lines 6-7 and 29-30). That is, in the bag 1 of the noted claims after a solvent is introduced into the bag and mixes with the soluble sterile product 10 in the bag 1, the reconstituted solution only partially fills a capacity of the bag 1. That allows the bag to be easily shaken to achieve a proper solution. (Substitute specification, page 7, lines 7-9). That also allows different quantities of soluble sterile product to be initially placed in the bag. (Substitute specification, page 7, lines 9-11).

Further, the bag 1 is hermetically sealed at its periphery to define a sterile closed space and has at least one port 2, 4 also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag 1. The passageway is closed by a pierceable membrane 6, 7 for introduction of a solvent into the bag 1 and respectively for withdrawal of the read to use solution from the bag 1.

Further, the bag 1 includes a port that has a plug 20. With that structure the reconstituted liquid can be removed by piercing a syringe port through the plug 20 and withdrawing the reconstituted solution from the bag 1. The plug 20 provides a structure such that when the syringe needle is removed the reconstituted solution in the bag 1 is not able to flow out of the bag 1. (Substitute specification, page 8, lines 8-13).

Claims 12-17 are similar to claim 6 except that claims 12, 14, and 17 are specifically directed to a "method for preparing solutions with predetermined concentrations of soluble sterile product in powder form". According to the methods of claims 12-17, a step is executed for feeding an amount of solvent into the bag that is less than the capacity of the bag, and individual doses of the reconstituted solution are then removed from the bag.

The present response also sets forth new claims 18-25 for examination. New dependent claims 18 and 19 depend from respective independent claims 14 and 16 and clarify that "the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag". That subject matter is supported by the original specification for example at page 7, first full paragraph, indicating that the bag capacity is preferably 1.5 and 2 times the volume of the solution to be prepared in it. Claims 18 and 19 merely recite the inverse of that feature by indicating that the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

New claims 20-25 are similar to claims 14-17 except that those claims are directed to "a method for using a sterile bag...". In those methods recited in claims 20-25 an operation is still executed of feeding an amount of solvent into the bag that is less than the capacity of the bag, and an operation is then executed for removing individual doses of the reconstituted solution from the bag.

To make the explanation of the claimed invention simplified, as a concrete example imagine that a sterile product in powder form to be stored within the bag is a crystalline antibiotic to be used for reconstituting injectable solutions in which the concentration of the biotic material must be exactly controlled at a specified value.

Before the claimed invention was made and exploited, it was common practice to use glass bottles containing single doses of antibiotic that was dissolved directly within the bottles by feeding water into the bottles. The thereby formed single dose solutions were then drawn into syringes to be injected into patents. Such an operation is demanding and costly, particularly at hospitals were such an operation has to be repeated a large number of times everyday. (Substitute specification, page 2, lines 17-31).

It is also not believed currently possible to prepare solutions of antibiotics in bags in suitable plants to then dispatch them to hospitals, because such solutions remain unaltered for a very short time. (Substitute specification, page 3, lines 1-4).

Addressing now specifically the rejection of claims 6-13 under 35 U.S.C. § 103(a) as unpatentable over Slater, Scharf, or Beigler, that rejection is traversed by the present response.

It is initially noted that each of the independent claims is amended by the present response to clarify a feature recited therein, and to further emphasize a beneficial feature in the claimed invention.

Specifically, independent Claim 6 now recites "wherein the at least one port of the bag is plugged by a plug, the plug configured to receive a syringe port through the plug to remove the reconstituted ready to use solution from the bag". The method claims now also recite a similar feature by requiring a step of "removing from the bag the reconstituted ready to use solution in individual dose sizes". The above-noted features are supported by the original specification, see for example the substituted specification at page 8, line 8 et seq., as a non-limiting example.

The above-noted claim amendments even further clarify structural and operating differences, and benefits, between the claimed invention and the applied art.

One benefit of the claimed invention is that the claimed bag is more simple to use than the previous operation of utilizing glass bottles containing single individual doses. In the claimed invention, multiple doses can be formed in a single bag, and then individual doses can be removed from the bag as needed. Such features as now clarified in the claims even further distinguish the claims over the applied art.

The outstanding rejection is correct in stating that each of the applied art to Slater, Scharf, and Beigler disclose hermetically sealed bags for preserving and transporting a determined amount of a soluble sterile product in powder form and for reconstituting a ready to use solution having a predetermined concentration of the sterile product.

However, each of the three references to Slater, Scharf, and Beigler have common features that have rendered the disclosed bags impractical for actual usage. Those common features are that in each of the bags, individual doses of reconstituted solution are not removed, and the bags must be completely filled with solvent. Such deficiencies in each of the bags in Slater, Scharf, and Beigler are believed to not be properly and fully considered in the outstanding rejection.

None of the applied art to Slater, Scharf, nor Beigler teach or suggest any operation in which individual doses of a reconstituted solution can be removed from a bag. The absence of such a teaching results because each of the bags disclosed in Slater, Scharf, and Beigler are directed to different types of bags not designed to form multiple doses of a solution in a bag, and to then remove individual doses of the solution from the bag multiple times as needed. As such, each of the claims are believed to clearly distinguish over the teachings in the applied art.

Moreover, the claims further distinguish over the applied art for reasons emphasized in the previous response, which are now repeated below.

The outstanding rejection also recognizes that none of Slater, Scharf, nor Beigler state that solvent should be added to a volume less than a capacity of the bag. To overcome that recognized deficiency in each of the applied art to Slater, Scharf, and Beigler, the outstanding Office Action states:

> Adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability to one of ordinary skill in the art; it is a simple matter of common sense. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag or 1.5 to 2 times the volume of the ready to use solution

> into the inventions of Slater, Scharf, and Beigler in order to provide room to shake the contents of the bag.[1]

The above-noted grounds for maintaining the outstanding rejection is traversed on the following aspects. First, the feature of allowing the bag to be easily shaken to achieve a proper solution as noted above is only one of the benefits achieved by the claimed invention. Another benefit is that the structure of the claimed invention allows different quantities of soluble, sterile product to be initially placed in the bag. In the devices in the cited art, as the bags are to be completely filled, they must always have the same initial amount of sterile product therein to achieve a desired concentration. In the claimed invention, since the bag is partially filled, a different amount of sterile product can be initially placed in the bag.

Moreover, in each of the cited art if the bag was only partially filed with a fluid, an improper concentration of the sterile product would result. That is, in each of the devices of Slater, Scharf, and Beigler a quantity of the sterile products provided in the bag initially is specifically selected so that when the bags are fully filled with a solvent an appropriate concentration is realized. By only partially filling the bags in Slater, Scharf, and Beigler, that appropriate concentration would not be achieved. Thus, the devices in Slater, Scharf, and Beigler would actually be ***inoperative*** if they were not completely filled with a solvent.

Further along those lines, what the outstanding Office Action disregards as obvious or "simple common sense" is clearly not obvious or simple common sense as it is ***directly contrary to what is actually taught in the applied references***. That is, each of the applied references, as discussed in further detail below, discloses completely filling a bag. As that is the case, it is unclear how the Office Action can indicate that a directly contrary operation to that actually disclosed in each of the cited references would be "simple common sense". Stated another way, how can it be "simple common sense" to do something contrary to the

[1] Office Action of April 22, 2003, page 3, lines 13-19.

express teachings in each of the cited references. It is respectfully submitted that, in fact, the applicants of the present invention have recognized drawbacks in conventional devices such as in the cited art, and have devised the novel solution of the present invention to address such drawbacks.

The claims are directed to storing a soluble solid product within a bag whose capacity is larger than the volume of the solution to be reconstituted therein. With the use of such a large bag, there is no need for the bag to have special shapes or include special devices to ensure proper solution of the soluble solid product in a solvent because the solid product can be quickly and completely dissolved by simply vigorously shaking the bags.

Obviously, when utilizing such a bag as claimed it is necessary to exactly measure the amount of solvent to be fed into the bag containing a measured amount of soluble solid compound. However, applicants submit that the benefits of the claimed invention overcome such a drawback as it is a simple, quick operation to introduce a desired dose volume of solvent into a bag, while it is of great practical importance to have the possibility of completely and quickly dissolving a soluble product originally stored in the bag.

Further, what is considered in the Office Action to be "common sense" would actually result in a drawback in the devices of Slater, Scharf, and Beigler. Specifically, in those devices, by completely filling the bags therein, it is not necessary to measure a volume of a solvent to be injected into the bags. Instead, the bags must just be completely filled.

In contrast to the teachings in Slater, Scharf, and Beigler, the claimed invention requires an extra step of properly measuring an amount of solvent to be introduced into the bag since the bag is not completely filled with the solvent. However, the applicants believe that the benefits of the present invention outweigh that inconvenience.

In further detail, the applied art to Scharf discloses that when a solution has to be reconstituted within a bag containing a fixed, predetermined amount of sterile product in

powder form, the bag must be completely filled with the solvent. That is evident from the disclosure in Scharf at column 8, line 62, column 9, line 23, column 6, lines 48-51, and the Tables in column 7 and column 8 in which it is clearly indicated that the total volume of the solution corresponds to the volume --one litre--of the bag.[2]

In such ways, what the Office Action indicates as "common sense" is actually directly contrary to the express disclosure in Scharf. Given that Scharf expressly discloses completely filling a bag, it is clear that it would not have been obvious to one of ordinary skill in the art to modify Scharf to not operate in that manner, particularly as no reference has been cited to even suggest not completely filling a bag such as in Scharf.

The cited art to Beigler also discloses a bag and a method that are substantially the same as those in Scharf because the amount of solvent to be introduced into the bag completely fills the bag.[3]

As Beigler is similar to Scharf, clearly Beigler also does not disclose or suggest what is indicated as "common sense" in the Office Action.

Similarly to Scharf and Beigler, Slater provides teachings in which a bag is completely filled with water to prepare a solution of granulated or powder material stored therein.[4]

In such ways, Slater also fails to teach or suggest what is noted in the Office Action as "common sense".

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[2] At column 8, line 62, Scharf specifically indicates "[t]he bag is allowed to ***fill***" (emphasis added); at column 9, lines 22-23, Scharf states "***filling*** will take approximately 10 minutes. Allow bag to ***fill***" (emphasis added). In the Tables in columns 7 and 8 Scharf discloses filling a one liter bag with one liter of solution.

[3] That is also evident from Example 1 in Beigler, column 9, line 48 et. seq., which indicates that a bag of capacity of 500 ml is "charged with 500 ml of sterile, pyrogen-free water to make the 5% aqueous dextrous solution" (column 10, lines 1-3), indicating that Beigler discloses completely filling a bag with solution.

[4] See Slater in the Abstract, column 3, lines 63-64, column 4, line 56, and column 5, line 6, all disclosing a bag being "filled". Slater also discloses filling a 6-8 liter bag at a rate of 1 liter per minute taking 6-8 minutes, again clearly indicating completely filling a bag in Slater (see column 5, lines 3-9).

Taken from another point of view, each of Scharf, Beigler and Slater teach that in order to prepare in a bag a solution having a desired well determined concentration of a soluble solid compound, a fixed amount of which is stored within the bag, the total internal volume of such a bag must be equal to the volume of the final solution reconstituted therein. In such ways, in those devices of Scharf, Beigler, and Slater it is not necessary to measure the volume of the solvent to be fed into the bag because the volume of the bag simply has to correspond to the final volume of the solution.

The problem with such an approach is that whenever a solvent is introduced into a bag to completely fill the bag, it is then difficult or even impossible to get a quick and complete dissolution of the solid material stored in the same bag.

For that reason, the bag of Scharf includes an internal mechanism within the inner side of the bag, and more particularly the bag is provided with an internal seal 14 for creating a turbulence when fluid flows into the bag 10 to ensure adequate mixing of the solute and solvent.[5]

Slater also explains that a bag must have a V-shape at a bottom interior to ensure that granules of solid material stored therein not only stay toward the bottom of the bag, but are also localized in a part where the water slowly flows, so that the granules stay suspended in a turbulent water flow to be dissolved.[6] The turbulent water flow swirls around the granules, thereby maximizing the surface area of the granules in contact with incoming water and the speed of water passing the granules.[7]

Moreover, since it is not possible to obtain a complete dissolution of a powered product, Beigler teaches using a filter to remove particulate matter from a reconstituted

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[5] See Scharf at column 1, lines 1-3, column 4, lines 43-45 and 56-60, column 2, lines 45-46, column 6, line 30, and column 10, lines 14 and 48.
[6] Slater at Claim 1, column 4, lines 65-68, and column 5, lines 1-9.

intravenous mixture,[8] which obviously brings about as a consequence that the concentration of the reconstituted solution cannot have a fixed predetermined value.

In such ways, the cited art to Slater, Scharf, and Beigler teaches only utilizing bags with internal volume equal to a final volume of an injectable solution reconstituted therein. As a result, such bags are further provided with devices for improving dissolution of the solid soluble materials stored therein.

Each of the currently pending independent claims recites the above-noted structure or operation that a bag is only partially filed with a solvent when reconstituting the ready to use the solution. Thus, each of the pending claims clearly distinguishes over the applied art.

Further, with respect to method claims 12-25, those claims are believed to be even further distinguish over the applied art as none of Slater, Scharf, or Beigler teach any operation in which a bag is filled to be less than completely filled, and in fact, as noted above, each of those references indicate completely filling a bag. Thus, those claims even more clearly distinguish over the applied art.

Addressing now the rejection of claims 6-17 under 35 U.S.C. § 103(a) as unpatentable over Schumann in view of Slater, Scharf, or Beigler, that rejection is traversed by the present response.

The above-noted rejection relies on the primary reference of Schumann to disclose a sealed plastic bag 13 for preserving and transporting a soluble product 51 in powder form. The Office Action recognizes certain deficiencies in Schumann as the Office Action states:

> In addition, Schumann does not specifically recite that the bag is hermetically sealed or made from polyolefin.[9]

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[7] Slater at column 4, lines 57-62.
[8] Beigler at, for example, Claim 11.
[9] Office Action of April 22, 2003, page 4, lines 7-8.

To overcome the recognized deficiencies in Schumann, the outstanding Office Actions cites that teachings in Slater, Scharf, and Beigler and states:

> ...it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided hermetic sealing and polyolefin material as taught by Slater, Scharf, and Beigler into the invention disclosed by Schumann, so as to keep the product from spoiling or being contaminated.[10]

The Office Action also recognizes that Schumann does not disclose the "claimed range of requiring multiple doses", but again the teachings in Slater, Scharf, and Beigler are relied upon for that feature on the basis that "it has been held that where the general conditions of the claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art".[11]

First, Applicants note that clearly the newly applied art to Schumann does not disclose or suggest any operation or even a possibility in which individual doses are removed from the bag. Schumann is not designed and could not even be modified to operate in such a manner. Therefore, no combination of Schumann in view of any of the further cited references could possibly meet the limitations now clarified in the claims.

Further, the position in the Office Action that Schumann could be modified to have a hermetically sealed bag "to keep the product from spoiling or being contaminated" is simply ***impossible***. In Figure 3 Schumann clearly discloses that the bag 13 must be filled with water to interact with the ingredient 51. As a result, it is clear that the bag 13 in Schumann is not ***hermetically sealed and could not be hermetically sealed***. If Schumann was modified to have a hermetically sealed bag, the device of Schumann would simply become ***inoperable*** for its intended purpose because the water could not be introduced therein. It is clear that the

[10] Office Action of April 22, 2003, page 4, lines 10-14.
[11] Office Action of April 22, 2003, the sentence bridging pages 4 and 5.

device of Schumann is designed, for example, for home use and not for trained medical uses as in the device of Slater, Scharf, and Beigler.

Moreover, along those same lines the teachings in Slater, Scharf, and Beigler are simply irrelevant to the device of Schumann. None of the teachings in Slater, Scharf, or Beigler are directed to or similar to a syringe for douching and enemas as in Schumann.

Further, with respect to the features in claims 7, 8, 10, 11, 13, 15, and 17, applicants submit that there is no teaching or suggestion for the device of Schumann to store multiple doses from one filling and the basis for the outstanding rejection thereto is not based on any teachings in the prior art references themselves. That is, applicants are not aware, and it seems to be difficult to believe that it would be the case, that the device of Schumann is designed so that one filling of water provides multiple doses. In fact, Schumann specifically is directed to a ***disposable*** syringe, which clearly implies only a single use. Also, the basis for the rejection to the above-noted claims based on "discovering the optimal workable ranges" is completely unclear, and particularly as to how controlling doses stored in a bag is an optimum or workable range.

In such ways, each of the pending claims is believe to also clearly distinguish over the combinations of Schumann in further view of Slater, Scharf, or Beigler.

As no other issues are pending in this application, it is respectfully submitted that the present application is now in condition for allowance, and it is hereby respectfully requested that this case be passed to issue.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER, & NEUSTADT, P.C.

Customer Number
22850

Tel.: (703) 413-3000
Fax: (703) 413-2220

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Gregory J. Maier
Registration No. 25,599
Surinder Sachar
Registration No. 34,423
Attorneys of Record